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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/523,400 | 11/14/2005 | Bernard Pau | P70365US0 | 6214 |

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| EXAMINER | |
|---|---|
| GAMETT, DANIEL C | |

| ART UNIT | PAPER NUMBER |
|---|---|
| 1647 | |

| MAIL DATE | DELIVERY MODE |
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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 10/523,400 | PAU ET AL. | |
| | Examiner | Art Unit | |
| | DANIEL C. GAMETT | 1647 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *29 January 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *1-35* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☒ Claim(s) *1-10,14-28 and 33-35* is/are allowed.

6)☒ Claim(s) *11-13 and 29-32* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *03 February 2005* is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *09/14/2005*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

## DETAILED ACTION

1. The preliminary amendments of 02/03/2005 have been entered in full. Claims 1-35 are under examination.

2. Applicants' request for a corrected filing receipt on 01/08/2008 is acknowledged. The request is being processed.

## Sequence Compliance Issues

3. 37 C.F.R. 1.821 provides that any unbranched sequence of four or more amino acids must be identified by a sequence identifier (SEQ ID NO.), and listed in the sequence listing. 37 CFR 1.821(d) requires the use of the assigned sequence identifier in all instances where the description or claims of a patent application discuss sequences regardless of whether a given sequence is also embedded in the text of the description or claims of an application. Claims 5, 6, 15-17, 19, and 35 recite amino acid sequences, depicted as formulas (I) (II), and (III), which do not appear in the Sequence Listing for this application. These formulas are similarly embedded throughout the specification. Claims 23, 24, and 26 recite sequences without recitation of the sequence identifiers. Applicant is required to submit a new sequence listing and make appropriate amendments to the specification and claims in order to bring the case into compliance.

***Claim Rejections - 35 USC § 112***

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claims 11-13 and 30-32 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claims 11, 12, 30, and 31 are incomplete for omitting essential steps. While all of the technical details of a method need not be recited, the claims should include enough information to clearly and accurately describe the invention and how it is to be practiced. The minimum requirements for method steps minimally include a contacting step in which the reaction of the sample with the reagents necessary for the assay is recited, a detection step in which the reaction steps are quantified or visualized, and a correlation step describing how the results of the assay allow for the determination. Claims 11, 12, 30, and 31 lack a correlation step. Claims 13 and 32 recite correlation but do not describe how the results of the assay allow for the determination. The claims instruct the skilled artisan to correlate but do not recite a relationship between the amount of antibody complexes and the clinical condition of the individual.

6. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

7. Claim 29 is rejected under 35 U.S.C. § 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. The invention appears to employ novel biological materials, specifically the the hybridoma 3D4 deposited on Jul. 31, 2003 with the CNCM under the No. CNCM I-3073. Since the biological materials are essential to the claimed invention, they must be obtainable by a repeatable method set forth in the specification or otherwise readily available to the public. If the biological materials are not so obtainable or available, the requirements of 35 U.S.C. § 112 may be satisfied by a deposit of the biological materials. It is noted that Applicants have deposited the biological materials (p. 52 of the specification), but there is no indication in the specification as to public availability. If the deposit is made under the Budapest Treaty, then an affidavit or declaration by Applicants, or a statement by an attorney of record over his or her signature and registration number, stating that the specific biological materials have been deposited under the Budapest Treaty and that the biological materials will be irrevocably and without restriction or condition released to the public upon the issuance of a patent, would satisfy the deposit requirement made herein. If the deposit has *not* been made under the Budapest Treaty, then in order to certify that the deposit meets the criteria set forth in 37 C.F.R. §§ 1.801-1.809, Applicants may provide assurance of compliance by an affidavit or declaration, or by a statement by an attorney of record over his or her signature and registration number, showing that:

   (a) during the pendency of this application, access to the invention will be afforded to the Commissioner upon request;

(b) all restrictions upon availability to the public will be irrevocably removed upon granting of the patent;
(c) the deposit will be maintained in a public depository for a period of 30 years of 5 years after the last request or for the effective life of the patent, whichever is longer;
(d) a test of viability of the biological material at the time of deposit will be made (see 37 C.F.R. § 1.807); and
(e) the deposit will be replaced if it should ever become unviable.

8. Applicant's attention is directed to MPEP § 2400 in general, and specifically to § 2411.05, as well as to 37 C.F.R. § 1.809(d), wherein it is set forth that "the specification shall contain the accession number for the deposit, the date of the deposit, the name and address of the depository, and a description of the deposited material sufficient to specifically identify it and to permit examination." The specification should be amended to include this information, however Applicants are cautioned to avoid the entry of new matter into the specification by adding any other information.

9. Claims 11-13 and 30-33 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for method of in vitro diagnosis of heart failure in a human, comprising bringing a blood sample into contact with an anti-proBNP(1-108) antibody as defined in claim 1, does not reasonably provide enablement for methods comprising all biological samples. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims. The instant specification asserts to show for the first time that circulating proBNP(1-108) is effectively a marker for predicting heart failure and that it is present at a concentration that is significantly higher in heart failure patients than in normal control individuals. Therefore, the prior art offers no guidance as to the

presence of proBNP(1-108) in all biological fluids or tissues. The specification shows experimental results wherein 14 blood samples from normal individuals and 15 blood samples from patients suffering from heart failure were tested by means of the proBNP(1-108) IRMA assay. The results obtained on the blood samples from patients suffering from heart failure are significantly higher than those obtained on the samples from normal individuals. No attempt was made to detect proBNP(1-108) is other biological samples, e.g. tears, saliva, or tissue biopsies. Without evidence that proBNP(1-108) is widely distributed in all tissues and/or fluids it is not certain that the instantly claimed methods would ever work on samples other than blood samples, regardless the amount of experimentation a skilled artisan might be willing to perform. It is further noted that the claims recite any biological sample, without even requiring that the sample should be obtained from the individual being tested.

***Conclusion***

10. Claims 11-13 and 29-32 are rejected.

11. Claims 1-10, 14-28, and 33-35 are allowable pending compliance with sequence rules.

12. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. WO 9732900 A1; US Patents 5786163, 6828107, 7341838; US Patent Application Publications 20050118662, 20050244902, and 20060110775.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Daniel C. Gamett, PhD., whose telephone number is (571)272-1853. The examiner can normally be reached on 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Manjunath N. Rao can be reached on 571 272 0939. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Daniel C Gamett/
Examiner, Art Unit 1647